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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,701	09/04/2003	Bruce G. Gold	899-66834	8587

7590

07/19/2004

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EXAMINER

NICHOLS, CHRISTOPHER J.

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/656,701	GOLD, BRUCE G.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher J Nichols, Ph.D.	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-54 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-34 and 37-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 23-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4 September 2003</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims **23-34** and **52-53**) in the reply filed on 10 June 2004 is acknowledged. Applicant's request to rejoin Groups I, III, and IV is hereby *granted*. Claims **23-34** and **37-54** are under examination. Claims **35-36** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. The remaining restriction requirement is still deemed proper and is therefore made FINAL.

### ***Status of Application, Amendments, and/or Claims***

2. The Preliminary Amendment filed 4 September 2003 has been received and entered in full.

### ***Sequence Rules***

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein. This application discloses an amino acid sequence on pp. 8 lines 3 and 7. Correction is required.

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### ***Specification***

4. The disclosure is objected to because of the following informalities: misspelled word "couponds" (pp. 2 line 16); unclear alteration (pp. 9 line 1). Appropriate correction is required.

### ***Claim Objections***

5. Claim **33** is objected to because of the following informalities: missing space "Claim33". Appropriate correction is required.

### ***Non-Statutory Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims **23-34** and **37-54** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-36 of U.S. Patent No. 5,968,921 (19 October 1999) Gold in view of U.S. Patent No. 5,026,381 (25 June 1991) Li.
7. US 5,968,921 teaches a method of stimulating nerve growth or regeneration in a mammal, comprising administering to the mammal a pharmaceutical compound that promotes

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disruption or interferes with assemble of a steroid receptor complex (claim 25). US 5,968,921 teaches this method wherein the compounds are geldanamycin and NGF and wherein said compounds cause hsp90 dissociated from the complex or prevent hsp90 association with the complex.

8. Regarding promoting nerve growth in a mammal having a spinal cord damage, the art recognizes that “stimulating nerve growth or regeneration in a mammal” substantially encompasses spinal cord (and nerve) damage thus meeting the limitations of claims 23, 37, and 54 (US 5,026,381 (Col. 1-2)).

9. Regarding gap-filling material, US 5,026,381 discloses a method of filling the gap between the distal and proximal ends of an injured nerve (including spinal cord damage) using a Type I collagen based gap-filling material to augment the recovery of said nerve thus meeting the limitations of claims 24, 32, 38, 39-47, and 54 (Example VIII; claims 1-2).

10. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use geldanamycin and NGF or other combinations of agents as listed in the claims for the instant application because their utility is disclosed in the claims of US 5,968,921 thus meeting the limitations of claims 25-31, 33-36, and 48-53 (US 5,968,921 claims 1-36). Further, US 5,026,381 teaches the use of improved, biocompatible material for grafting a damaged nerve (Col. 2-4).

11. The person of ordinary skill in the art would have been motivated to make those modifications because nerve growth and regeneration will accomplish the same goal of nerve repair and nerve growth as claimed in the instant application. Nerve growth, regeneration, and/or repair at the time of the invention was seen as a desirable outcomes for treating nerve damage,

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including spinal cord injury. In addition, US 5,026,381 teaches improved results using a Type I collagen-based nerve grafting material (Col. 5 lines 39-68).

***Summary***

12. No claims are allowed.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN  
July 9, 2004

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**